

App. No. 10/045,553  
Reply to Office Action of October 24, 2003  
Atty Ref. No.: P-10289,00 US

### **REMARKS**

This amendment is responsive to the Office Action dated October 24, 2003. In this Amendment, Applicants have amended claims 1, 5, 6, 9 and 10 and added new claims 12-21. Accordingly, claims 1-21 are pending.

### **Supplemental Information Disclosure Statement filed October 29, 2003**

As a preliminary matter, Applicants bring to the Examiner's attention the submission of a Supplemental Information Disclosure Statement on October 29, 2003. The Supplemental Information Disclosure Statement was submitted after the issuance of the Office Action of October 24, 2003. Pursuant to 37 C.F.R. § 1.97(e)(1), however, Applicants state that each item of information contained in the Supplemental Information Disclosure Statement of October 29, 2003 was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Supplemental Information Disclosure Statement. Accordingly, Applicants respectfully request that the Examiner consider the Supplemental Information Disclosure Statement, and indicate such consideration in his next communication.

### **Claim Rejection Under 35 U.S.C. § 112, first paragraph**

In the Office Action, the Examiner rejected claims 1-11 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner stated that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and use the invention. In particular, the Examiner stated that it is not clear from the disclosure how the stylet handle grips and releases the lead body. Applicants respectfully traverse this rejection.

Applicants' disclosure, including the specification and drawings, adequately describes the features set forth in the claims, for purposes of enablement. One skilled in the art of medical lead design would have no difficulty making and using the claimed invention without undue experimentation. On the contrary, given the structural embodiments described and illustrated in Applicants' disclosure, those skilled in the art would readily appreciate how to make and use the

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claimed invention. Below, Applicants focus attention on the aspects of the claimed invention that the Examiner apparently found to be lacking of enablement.

First, the Examiner made reference to limitations related to gripping the lead body. Applicants' disclosure adequately describes an exemplary gripper 58 to aid in gripping a lead body within a lead carrier of a stylet handle. At paragraph [0005], for example, the specification describes a stylet handle with a lead carrier and at least one gripper carried in the lead carrier configured to grip the lead body at a selected point along the lead body.

Moreover, FIGS. 5, 6, 8, 9 and 10 each depict a gripper 58 within a lead carrier 56 formed in stylet handle 52. At paragraph [0022], the specification states, with reference to FIGS. 5-11, that the "stylet handle 52 has a lead carrier 56 and at least one gripper 58 carried in the lead carrier 56 configured to grip the lead body 43." Paragraph [0022] further states that "lead carrier 56 is designed so a thumb or forefinger has room to push the stimulation lead 40 into the lead carrier 56."

At paragraph [0024], the specification indicates that "the lead body 43 is pressed 70 into the lead carrier 56 in the stylet handle 52 by pressing the lead body 43 into the lead carrier 56 using the thumb or forefinger." In this manner, with reference to paragraph [0024], the "lead carrier 56 is designed so a thumb or forefinger has room to push the stimulation lead 40 into the lead carrier 56. By pushing the lead body 43 into the lead carrier 56 the lead body 43 is gripped with at least one gripper 58 in the lead carrier 56."

The gripper 58 is clearly depicted in FIGS. 5, 6, 8, 9, and 10. In FIG. 8, in particular, it is clear that, in one embodiment, a gripper 58 may take the form of one or more indentations that extend into the channel-like lead carrier 56. Upon pressing a lead into lead carrier 56, e.g., with thumb or forefinger, the protruding indentations grip the lead to secure it within lead carrier 56. In view of this disclosure, one skilled in the art would have no difficulty making and using an embodiment of the claimed invention, including a feature suitable to grip a lead body.

Second, the Examiner referred to limitations relating to releasing the lead body. Applicants point out that the claims do not recite such a limitation. Although the embodiment described above, i.e., gripping indentations, would permit release of a lead body, this feature simply is not recited per se by the claims. Nevertheless, just as the lead is pressed into the lead carrier, it could be pulled from the lead carrier.

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Although the claims do not refer to a lead release, some claims do recite a feature of a stylet handle called a "stylet release." According to claim 4, for example, the stylet release has an engaged position where the stylet wire is coupled to the stylet handle and a disengaged position where the stylet wire is decoupled from the stylet handle. According to this limitation, the stylet may be removed from the stylet handle to create a "lead opening."

A lead opening 62 is clearly described in the specification and illustrated in FIG. 9. In an exemplary embodiment, the lead opening 62 permits the stylet handle to be moved toward a lead distal end of the lead body without being encumbered by the stylet wire. In an embodiment described in paragraph [0023], the proximal end of the lead may move through the lead opening 62 in stylet handle 52, allowing the stylet handle 52 to engage the stimulation lead 40 anywhere on the lead body. Therefore, if the Examiner was referring to the "stylet release," it is clear from the specification and drawings that one skilled in the art of lead design would have no difficulty making and using a stylet handle with such a feature.

In view of the depth of detail provided in Applicants' disclosure, one skilled in the art of lead design would be able to readily make and use the claimed invention without undue experimentation. Therefore, Applicants respectfully submit that the disclosure satisfies the enablement requirements of 35 U.S.C. § 112, first paragraph, and request that the Examiner withdraw the rejection of claims 1-11 under 35 U.S.C. § 112, first paragraph.

#### **Claim Rejection Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claims 1-11 under 35 U.S.C. § 103(a) as being unpatentable over Duysens et al. (U.S. 6,104,960) in view of Borkan (U.S. 6,510,347 and either Lauro (U.S. 6,154,678), Intelkofer et al. (U.S. 4,858,810) or Lynch et al. (U.S. 5,448,993).

In support of the rejection, the Examiner cited Duysens et al. as disclosing "a neurological implant system for locating an electrode in a patient adjacent the spinal column," including "an electrode, stylet wire and a handle 170 for gripping the electrode and wire." The Examiner stated that Duysens et al. does not disclose "the specifics of the electrode and the handle claimed."

The Examiner cited Borkan, however, as disclosing a spinal cord stimulating lead with a closed end to form a stop for a stylet wire. In addition, the Examiner cited Lauro, Intelkofer et al. and Lynch et al. as disclosing handles designed to engage and release a wire.

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On this basis, the Examiner concluded that it would have been obvious to modify the Duysens et al. device, apparently to provide a closed lead per the teachings of Borkan, "to provide a more efficient system." The Examiner further concluded that it would have been obvious to use a "feed of the type disclosed by either Lauro, Intlekofer et al. or Lynch et al. in place of that disclosed by Duysens et al. . . . given that it provide better control of the elements."

Applicants respectfully traverse this rejection, to the extent the rejection may be considered applicable to the claims, as amended. The applied references fail to disclose or suggest the inventions defined by Applicants' claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Contrary to the requirements of pending claims 1-4 and 12, for example, the applied references fail to disclose or suggest an implantable neurological stimulation lead with improved stylet handle comprising a lead body with at least one electrical connector, at least one electrode, a stylet wire configured for insertion into a stylet lumen in the lead body, and a stylet handle connected to the stylet wire, the stylet handle having a lead carrier and at least one gripper carried in the lead carrier configured to grip the lead body at any selected point along the lead body between the body distal end and the body proximal end. The applied references also lack any teaching that would have suggested a lead carrier that defines a channel-like recess to accommodate a portion of the lead body when the lead body is pushed laterally into the channel-like recess for engagement with the gripper, as set forth in claim 12.

Similarly, with respect to claims 5 and 13, none of the applied references suggests an implantable neurological stimulation lead with improved stylet handle comprising a lead body with at least one electrical connector, at least one electrode, a stylet wire configured for insertion into a stylet lumen to stiffen the lead body, and a stylet handle means, selectively connected to the stylet wire, configured to grip the lead body at any selected point along the lead body between a body distal end and a body proximal end. Unlike claim 13, the applied references provide not teaching that would have suggested a stylet handle means that defines a channel-like recess to accommodate a portion of the lead body when the lead body is pushed laterally into the channel-like recess for engagement with the gripper.

The applied references also lack any teaching that would have suggested a stylet for an implantable neurological stimulation lead comprising a stylet wire configured for insertion into a

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stylet lumen to stiffen a lead body; and a stylet handle connected to the stylet wire and having a lead carrier and at least one gripper carried in the lead carrier configured to grip the lead body at any selected point along the lead body between a distal end of the lead body and a proximal end of the lead body, as defined by claims 6-8 and 14. With respect to claim 14, the applied references clearly fail to teach a lead carrier that defines a channel-like recess to accommodate a portion of the lead body when the lead body is pushed laterally into the channel-like recess for engagement with the gripper.

With respect to claims 9 and 15, the applied references also fail to disclose or suggest a stylet for an implantable neurological stimulation lead comprising a stylet wire configured for insertion into a stylet lumen to stiffen a lead body, and a means for grasping the lead body selectively connected to the stylet wire, the means for grasping configured to grip the lead body at any selected point along the lead body between a distal end of the lead body and a proximal end of the lead body. Further, unlike claim 15, the applied references do not teach a grasping means that defines a channel-like recess to accommodate a portion of the lead body when the lead body is pushed laterally into the channel-like recess, and a gripper within the channel-like recess.

Finally, contrary to the requirements of claims 10, 11, and 16, the applied references fail to disclose or suggest a method for inserting a stylet in a neurological stimulation lead, comprising inserting a stylet wire into a stylet lumen, stopping insertion of the stylet wire when the stylet wire contacts a stylet stop in the stylet lumen of a lead body distal end, inserting the lead body in a stylet handle lead carrier, and gripping the lead body at any selected point along the lead body between a lead body distal end of and the lead body proximal end with at least one gripper located in the stylet handle lead carrier while the stylet wire remains in contact with the stylet stop in the stylet lumen in the lead body distal end. With respect to claim 16, the applied references neither disclose nor suggest the use of a stylet handle defining a channel-like recess to accommodate a portion of the lead body and the gripper is located within the channel-like recess, and gripping the lead body by pushing the lead body laterally into the channel-like recess for engagement with the gripper.

New claims 17-21 are similarly distinguishable over the applied references. Claims 17-21 require a device for implanting a neurostimulation lead comprising a stylet wire for insertion

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into a stylet lumen in a neurostimulation lead, and a stylet handle connected to the stylet wire, the stylet handle having a lead carrier and at least one gripper carried in the lead carrier configured to grip the lead at a selected point along the lead, wherein the lead carrier defines a channel-like recess to receive the lead when the lead is pushed laterally into the channel-like recess, and the gripper includes one or more indentations that extend into the channel.

None of the prior art applied by the Examiner would have suggested structure or methods to support the gripping of a lead body at any selected point. For example, the stylet handle disclosed by Duysens et al. includes a skirt 171 to engage only a proximal end of a lead. Borkan does not appear to describe a stylet handle, and therefore provides no teaching pertinent to this feature of the claimed invention.

Lauro describes a stimulation lead connector having a hole 26 for receiving a proximal end of a lead, and contacts 42 to a proximal connecting portion of the lead. Lauro does not suggest structure for gripping a lead body at any selected point along the lead body between the distal end and the proximal end, as set forth in the claims.

Intlekofer et al. and Lynch et al. disclose devices for manipulating guidewires, but make no mention of stylet handles capable of gripping neurostimulation leads as defined by the pending claims. Therefore, one of ordinary skill in the art of lead design would have found no teaching within Intlekofer et al. or Lynch et al. that would have suggested modification of the Duysens et al. system to include structure capable of gripping a lead at any point between the proximal and distal end of the lead.

Notably, none of the applied references provides any teaching remotely suggestive of the additional limitations set forth in claims 12-16, i.e., a channel-like recess to accommodate a portion of a lead body upon pushing the lead body laterally into the channel-like recess for engagement with a gripper.

In view of the above differences, none of the applied references would have suggested the desirability of modification of Duysens et al. to incorporate the features set forth in the amended claims. Therefore, the obviousness rejection under 35 U.S.C. § 103 should be withdrawn.

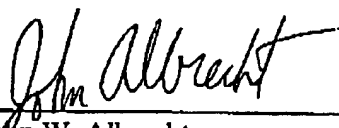
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### CONCLUSION

All claims in this application are in condition for allowance. Applicants respectfully request reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 13-2546. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Respectfully submitted,

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